

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION

16/FEB/2016

MEMORANDUM

Subject: Name of Pesticide Product: A20903A
EPA Reg. No./File Symbol: 100-RLIT
DP Barcode: D430648
Decision No: 510946
PC Codes: 071503 (fludioxonil), 129223 (sedaxane),
060109 (thiamethoxam)

From: Eugenia McAndrew, Biologist

Through: Masih Hashim, Ph. D., Team Leader Toxicology
Chemistry, Inerts and Toxicology Assessment Branch
Registration Division (7505P)

To: Jacquelyn Marchese, RM Team 01
Invertebrate and Vertebrate Branch 3
Registration Division (7505P)

Applicant: Syngenta Crop Protection, LLC
410 Swing Road
P.O. Box 18300
Greensboro, NC 27419-8300

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt</u>
Fludioxonil	2.17
Sedaxane	2.17
Thiamethoxam	22.80
<u>Other ingredients:</u>	<u>72.86</u>
Total:	100.00%

ACTION REQUESTED: The Risk Manager requests review of acute tox data submitted for 100-RLIT.

BACKGROUND: Syngenta Crop Protection, LLC has submitted acute toxicity studies with MRIDs 497122-06 to -11 to support the registration of the proposed product, A20903A, EPA File Symbol 100-RLIT. The submission includes a basic CSF and one alternate CSF dated

August 10, 2015, label, data matrix and company letter. The CSFs must be reviewed and accepted by the product chemists in the Chemistry, Inerts and Toxicology Assessment Branch.

GLP: Yes

DEVIATIONS: None

LABELING:

PRODUCT ID #: 000100-01587

PRODUCT NAME: A20903A

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear: Long-sleeved shirt and long pants, socks and shoes.

First Aid:

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

User Safety Recommendations:

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change clothing.

DATA EVALUATION RECORD

Product Reg. No.: 100-RLIT

Product Name: A20903A

1. DP BARCODE: 430648				
2. PC CODES: 071503, 129223, 060109				
3. CURRENT DATE: February 16, 2016				
4. TEST MATERIAL: Sedaxane/ fludioxonil/ thiamethoxam FS A20903A [Batch ID SMU4JP004; PSL Reference # 150224-11H; sedaxane 2.15% w/w or 24.7 g/L, SYN508210 (trans-isomer of sedaxane) 1.86% w/w or 21.4 g/L, SYN508211 (cis-isomer of sedaxane) 0.290% w/w or 3.33 g/L, fludioxonil 2.17% w/w 24.9 g/L and thiamethoxam 23.6% w/w or 271 g/L; density 1.106 g/ml; red liquid]				
Study/Species/Lab Study # /Date	MRID	Results	Tox Cat	Core Grade
Acute oral toxicity / rat Product Safety Labs Study #40541/April 22, 2015 OCSPP 870.1100; OECD 425	49712206	LD ₅₀ Females > 2000 mg/kg 6 animals were tested at Limit doses of 5000 or 2000 mg/kg Mortality: 5000 mg/kg: 1/1 2000 mg/kg: 0/5 5000 mg/kg (1 animal): The animal died within 5 ½ hours of test substance administration. Prior to death, the animal was hypoactive and exhibited irregular respiration, hunched posture and slight tremors. Gross necropsy revealed a distended stomach filled with fluid and fluid filled intestines. 2000 mg/kg (5 animals): All animals survived and gained weight. Clinical signs of toxicity included red feces in all animals and hypoactivity and irregular respiration in 3/5 animals with recovery by day 3. No gross abnormalities were noted at necropsy.	III	A
Acute dermal toxicity / rat Product Safety Labs	49712207	LD ₅₀ > 5000 mg/kg (both sexes)	IV	A

Study #40542/April 22, 2015 OCSP 870.1200; OECD 402		<p>All animals survived and gained weight. Dermal irritation (erythema) was noted at one female dose site on day 1 only. No other clinical signs of toxicity were observed. No gross abnormalities were observed at necropsy.</p> <p>Red staining was noted at all dose sites.</p>		
Acute inhalation toxicity / rat Product Safety Labs Study #40543/April 22, 2015 OCSP 870.1200; OECD 403	49712208	<p>$LC_{50} > 5.14$ g/L</p> <p>MMAD = 2.09μm GSD = 2.29</p> <p>All animals survived. Two animals lost weight by day 3 but all animals gained weight by day 7 and thereafter. All animals exhibited irregular respiration with recovery by day 2. No gross abnormalities were observed at necropsy.</p>	IV	
Primary eye irritation / rabbit CiToxLAB Hungary Ltd. Report #15/079-005N/July 15, 2015 OCSP 870.1300; OECD 405	49712210	<p>3 males tested; ocular anesthetic used pH 6.21</p> <p>No corneal opacity, iritis or positive scores were observed. Conjunctivitis (redness and/or chemosis) with score of 1 was observed in all eyes at one and 24 hours. Discharge score of 2 (not a positive effect) was noted in all eyes at one hour. All eyes were free of irritation by 48 hours.</p>	IV	A

Primary dermal irritation / rabbit Product Safety Labs Study #40544/April 22, 2015 OCSPP 870.2500; OECD 404	49712209	PDI = 0.0 3 females tested No dermal irritation was observed at any treated site.	IV	A
Dermal sensitization/mouse Product Safety Labs Study #40545/April 22, 2015 OCSPP 870.2600; OECD 429	49712211	Negative for sensitization % tested SI Value* 25% 0.83 50% 1.07 100% 0.77 *Stimulation Index values < 3 are are negative results. Results of concurrent positive control study are acceptable.	--	A

**Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap
W = Waived**